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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,697	07/25/2001	Nicholas C. Nicolaides	MOR-0040	5193

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/912,697	Applicant(s) NICOLAIDES ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29 and 35-41, drawn to methods for generating antibiotic resistant bacteria and to bacteria produced by those methods, classified in class 435, subclass 440.

II. Claims 30-34, drawn to methods for identifying mutant genes conferring antibiotic resistance, classified in class 536, subclass 23.7.

Each of Groups I and II above, comprise of multiple inventions as described below. herefore, restriction to one of the following is also required under 35 USC 121.

For Group I above, restriction is also required among inventions A-C, and, if A is elected, restriction and election is also required among the Groups A1-A3. The Groups are as follows:

(A) An invention of Group I wherein the method comprises a step of blocking mismatch repair in the bacterium.
(A1) An invention of Group A wherein the step of blocking the mismatch repairs comprises introducing a dominant negative allele into the bacterium.
(A2) An invention of Group A wherein the step of blocking the mismatch repairs comprises introducing an antisense molecule to the bacterium.
(A3) An invention of Group A wherein the step of blocking the mismatch repair comprises exposing the bacterium to a compound inhibiting mismatch repair.

(B) An invention of Group I wherein the method comprises culturing a bacterium with a natural defect in mismatch repair.

(C) An invention of Group I wherein the method comprises over-expressing the bacterial mismatch repair gene.

Group A3 also comprises further subgroups of inventions. Therefore, if this Group is elected, further restriction and election is required among the following Groups, each of which comprises the use of a different type of chemical compound to block bacterial mismatch repair. The groups within Group A3 comprise the method wherein:

(i) An invention of Group A3 wherein the compound used is an anthracene derivative.

(ii) An invention of Group A3 wherein the compound used is an ATP analog.

(iii) An invention of Group A3 wherein the compound used is a nuclease inhibitor.

(iv) An invention of Group A3 wherein the compound used is a DNA polymerase inhibitor.

For Group II above, restriction is also required among inventions D-G. The Groups are as follows:

(D) An invention of Group II wherein the genes of the wild-type and mutant bacterium are compared by sequence analysis.

(E) An invention of Group II wherein the genes of the wild-type and mutant bacterium are compared by microarray analysis.

(F) An invention of Group II wherein the genes of the wild-type and mutant bacterium are compared by introducing gene fragments from a mutant bacterium into wild-type bacteria, selecting bacteria that gained antibiotic resistance, and sequencing the gene fragment.

(G) An invention of Group II wherein the genes of the wild-type and mutant bacterium are compared by introducing gene fragments from a wild-type bacterium into mutant bacteria, selecting bacteria that have antibiotic resistance, and sequencing the gene fragment.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to methods that perform different functions. In the case of Group I, the methods produce antibiotic resistant bacteria. However, the methods of Group II are assays for the identification of a gene conferring such resistance. As the methods perform different functions, and as they are not disclosed as usable together, the methods are distinct.

3. The inventions of Groups A-C, Groups D-G, Groups A1-A3, and Groups (i)-(iv) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the methods of groups A-C involves a different method of producing an antibiotic resistant bacterium. However, each of the groups involves a different mode of operation in producing the bacterium. In the case of Groups A-C, each method comprises a different method of making a bacterium hypermutable. Groups D-G each relate to a method comprising a different method of comparing bacterium. In the cases of Groups A1-A3, each of the methods involves the use of a different type of molecule to block mismatch repair. In the case of Groups (i)-(iv), each of the methods involves the use of a different compound to block mismatch repair. In each case, the differences among the methods represent a different mode of operation. As the methods are not disclosed as usable together, and as they each have different modes of operation, the methods are distinct.

Species Election

4. For the purposes of this restriction, claim 6 is being treated as though the applicant had inserted the chemical formula at the top of page 20 of the specification into the claim. If this is in error, the applicant is requested to correct the mistake in the response to this action.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods of generating antibiotic resistant bacteria by using one of the ten anthracene derivatives of claim 7 to inhibit mismatch repair.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

held to be allowable. The applicant is required to elect one of the ten species disclosed in claim 7. Currently, claim 6 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Information Disclosure Statement

5. The information disclosure statement filed December 31, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Examiner's Notes

6. The examiner would like to draw the applicant's attention to claim 6 of the application. In claim 6, the applicant used the introduction: "The method of claim 5 wherein said compound is an anthracene derivative having the formula:" However, the claim does not include a formula, but merely begins to recite the constituents of the R groups of an unknown formula. Although the examiner treated the claim as containing the formula on page 20 of the specification for the purposes of the restriction, correction of the claim is required in the response to this action if the applicant elects Groups A3 and Group (i), and wishes to avoid a 35 U.S.C. 112, ¶2 rejection of the claim.

Conclusion

7. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
August 26, 2002

JAMES HOUSEL 9/9/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600